[redacted]

IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

SEAGEN INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	CASE NO. 2:20-cv-00337-JRG
	)	
DAIICHI SANKYO CO., LTD.,	)	
	)	[redacted]
Defendant, and	)	
	)	
ASTRAZENECA PHARMACEUTICALS LP and ASTRAZENECA UK LTD.,	)	
	)	
Intervenor-Defendants.	)	

DEFENDANTS' OPPOSITION TO PLAINTIFF'S MOTION TO STRIKE PORTIONS OF THE EXPERT REPORTS OF JOHN M. LAMBERT, PH.D.

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I. INTRODUCTION

Dr. John Lambert is a leading pioneer of the antibody-drug conjugate field, having helped to invent one of the first marketed ADCs and written several books on ADCs.[1] Seagen did not serve substantive responses to many of his opinions, and instead tries to exploit a process intended to prevent unreliable evidence from being heard by the trier of fact to prevent Dr. Lambert from appropriately presenting reliable and relevant scientific opinions to the jury—opinions that also happen to be contrary to Seagen's arguments.[2] Seagen's purported "Motion to Strike" nowhere cites, let alone applies, the governing Rule 702.[3] It should be denied.

II. IT IS APPROPRIATE FOR THE JURY TO HAVE AN OPPORTUNITY TO EVALUATE DR. LAMBERT'S FULL TESTIMONY AS SET FORTH IN HIS RESPONSIVE REPORT

A. Dr. Lambert Provides Necessary Analysis Regarding the POSA's Understanding of the Asserted Claims as a Whole

Rather than move for summary judgment of infringement, Seagen attempts to undercut Dr. Lambert's ability to present evidence and conclusions regarding non-infringement to the jury by falsely accusing him of disregarding the Court's claim construction rulings.[4] Dr. Lambert's Responsive Report and testimony, however, appropriately present his full non-infringement analysis, and the jury should have an opportunity to decide this disputed issue based on the complete record.

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[1] Ex. 1, Lambert Opening Report ¶¶ 8-16, Tab 1.
[2] *See Mobility Workx, LLC v. Cellco P'ship*, No. 4:17-CV-00872, 2019 WL 5721814, at *6 (E.D. Tex. Nov. 5, 2019) ("Put simply, a court 'is not concerned with whether the opinion is correct, but whether the preponderance of the evidence establishes that the opinion is reliable.'") (citing *Wallis v. Hornbeck Offshore Operators*, 2014 WL 3809743, at *1 (E.D. La. Aug. 1, 2014)).
[3] In filing this motion, Seagen also failed to meaningfully meet and confer with Defendants, as required, so as to allow an opportunity to clarify Seagen's apparent misinterpretations.
[4] Seagen's Motion to Strike Portions of the Expert Reports of John M. Lambert § II.A, *Seagen Inc. v. Daiichi Sankyo Co., Ltd.*, No. 20-00447-JRG (E.D. Tex. Jan. 6, 2022) (Dkt. No. 252).

[redacted]

In order to provide his expert conclusions regarding the alleged infringement by the accused product, DS-8201, Dr. Lambert's Responsive Report appropriately includes a comparison between the Asserted Claims as a whole and the accused product.[5] While the Court construed certain terms in its Claim Construction Order, which Dr. Lambert references and explicitly applies in his analysis, it also specifically stated that portions of the terms and phrases have their "plain and ordinary meaning."[6] Further, other aspects of the claim language and limitations of the Asserted Claims as a whole were never at issue during the *Markman* proceedings, and so are given their "plain and ordinary meaning" as well.[7] Those plain and ordinary meanings are not assessed "in the abstract," but rather must reflect the "meaning to the ordinary artisan after reading the entire patent."[8]

Consistent with these facts and legal principles, to establish the scope of the claims as a whole, including the meaning of each limitation, Dr. Lambert sets forth and applies each of the Court's constructions. For those aspects of the claim language that the Court did not interpret, Dr. Lambert explains and uses the plain and ordinary meaning as understood by the person of ordinary skill in the art ("POSA")[9], which is determined in the context of the entire patent.[10] An opinion that the POSA would find the accused product does not meet a claim limitation constitutes a non-infringement opinion, and does not amount to claim construction.[11] Instead, it "constitutes a

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[5] *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1324 (Fed. Cir. 2003).
[6] Markman Order, Dkt. 155 at 15, 41-42.
[7] *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005).
[8] *See Eon Corp. IP Holdings LLC v. Silver Spring Networks, Inc.*, 815 F.3d 1314, 1320 (Fed. Cir. 2016).
[9] *See, e.g.,* Ex. 2, Lambert Responsive Report ¶ 26.
[10] *See Phillips*, 415 F.3d at 1312 (explaining it is the "meaning to the ordinary artisan after reading the entire patent.").
[11] *See GREE, Inc. v. Supercell Oy*, No. 2:19-cv-71-JRG-RSP, 2020 WL 3893697, at *2 (E.D.

[redacted]

non-infringement opinion" that is properly presentable to the jury.[12] For terms given their plain and ordinary meaning, the "jury is free to apply an expert's description of the claims if it is consistent with the jury's understanding."[13]

In particular, Dr. Lambert's report discusses the Drug Moiety Intracellular Cleavage Limitation as a whole[14], and concludes that DS-8201 does not meet this limitation, as it would be understood by the POSA. In reaching this conclusion, Dr. Lambert used the Court's constructions, where applicable, as well as the plain and ordinary meaning, as understood by the POSA in the context of the entire patent, for portions of the claim the Court did not construe.[15]

In its Claim Construction Order, the Court specifically noted that "[t]he claim itself does not have an express requirement on the meaning of 'free drug,' how the free drug moiety dissociates, and whether the free drug dissociates as a result of a separate step. However, the claim expressly requires 'intracellularly cleaved,' and the specification defines that term."[16] The Court also stated the rest of the phrase has its plain and ordinary meaning.[17] Dr. Lambert therefore

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Tex. July 9, 2020). Dr. Lambert's deposition testimony also in no way implies he was offering claim constructions, as Seagen alleges. Instead, the discussion Seagen highlights addresses the POSA's understanding of the Drug Moiety Intracellular Cleavage Limitation as a whole, including aspects that, under this Claim Construction order, have their plain and ordinary meaning. Ex. 4, Lambert Tr. at 130:12-135:23.

[12] *See GREE*, 2020 WL 3893697, at *2.

[13] *Hitachi Consumer Elecs. Co. v. Top Victory Elecs. (Taiwan) Co.*, No. 2:10-CV-260-JRG, 2013 WL 5273326, at *10 (E.D. Tex. Sept. 18, 2013).

[14] Ex. 2, Lambert Responsive Report ¶ 11 ("wherein the drug moiety is intracellularly cleaved in a patient from the antibody of the antibody-drug conjugate or an intracellular metabolite of the antibody-drug conjugate").

[15] *See, e.g.,* Ex. 2, Lambert Responsive Report ¶ 51.

[16] Markman Order, Dkt. 155 at 40-42.

[17] *Id.* at 42. As Dr. Lambert expressly followed the Court's directive of using the plain and ordinary meaning, Seagen's reliance on *BMC Software, Inc. v. ServiceNow, Inc.*, No. 2:14-cv-903-JRG, Dkt. 325, slip op (E.D. Tex. Jan. 28, 2016), where the expert attempted to opine on the meaning of a term that the Court considered and expressly rejected, is not appropriate here.

[redacted]

applied the constructions provided by the Court and followed the Court's directive that the rest of the phrase has its plain and ordinary meaning.

Based on this analysis, Dr. Lambert explained [redacted].[18] This is also precisely what Claim 1's structure depicts: D is the portion of the molecule that is not Spacer (Y_y) or tetrapeptide (W_w). Dr. Lambert then analyzes [redacted]. Seagen's expert analyzes the structure differently. Who is right poses a classic factual question for the jury.[19]

B. Dr. Lambert's Opinions are Based on His Own Scientific and Technical Knowledge and Consistent with the Record

In Section I.B, Seagen mischaracterizes Dr. Lambert's Responsive Report [redacted].[20] Dr. Lambert, however, independently evaluated the information cited by Dr. Bertozzi, [redacted].[21] The cases Seagen cites are

[18] Unlike in *PerdiemCo, LLC v. Industrack LLC*, No. 2:15-CV-727-JRG-RSP, 2016 WL 6432699, at *1 (E.D. Tex. Oct. 28, 2016), where the expert argued for a special meaning after claim construction, Dr. Lambert uses the context of the '039 patent, which draws a distinction between releasing drug-linker compounds and releasing drug moieties, yet only claims ADCs where "***the drug moiety*** is intracellularly cleaved in a patient." *See* Ex. 2, Lambert Responsive Report ¶ 53 (citing '039 patent at 159:9-19 and Claim 1). Dr. Lambert's non-infringement analysis thus does not contradict the Court's construction, as Seagen alleges, but rather provides analysis on the plain and ordinary meaning of the rest of the phrase, which requires the intrinsic record for context.

[19] *See Hitachi*, 2013 WL 5273326, at *10.

[20] Dkt. No. 252 at 4.

[21] *See* Ex. 2, Lambert Responsive Report ¶¶ 143, 145.

[redacted]

thus inapposite.[22] Questions directed to what weight Dr. Lambert's substantive opinions should be given, [redacted], are appropriately left to the jury.[23]

Dr. Lambert's opinion that conjugating to an MC group on an antibody was known publicly prior to the claimed priority date of the '039 patent [redacted], is based on his own review of the prior art, [redacted].[24] [redacted][25], [redacted].[26] [redacted], they are relevant to issues of the credibility and reliability of the provided evidence and opinions, and so are relevant for the jury to consider.[27] Striking this discussion also will prejudice Defendants, as it would deprive the jury of additional

[22] *See GREE, Inc. v. Supercell Oy*, No. 2:19-cv-70-JRG-RSP, Dkt. 354, slip op. at 4 (E.D. Tex. July 26, 2020) (striking testimony where experts used facts and information learned only from conversations with individuals not disclosed under Rule 26 to form the basis of their opinions); *see also United Servs. Auto. Ass'n v. Wells Fargo Bank, N.A.*, No. 2:18-cv-366-JRG-RSP, 2019 U.S. Dist. LEXIS 219186, at *10–11 (E.D. Tex. Dec. 19, 2019) (same).

[23] *Mobility Workx*, 2019 WL 5721814, at *6 ("In determining the admissibility of expert testimony, proper deference should be accorded to the role of the jury 'as the arbiter of disputes between conflicting opinions.'") (citing *United States v. 14.38 Acres of Land, More or Less Situated in Leflore County*, 80 F.3d 1074, 1077 (5th Cir. 1996)).

[24] Ex. 2, Lambert Responsive Report IX.C.

[25] *See* Ex. 2, Lambert Responsive Report ¶¶ 143, 145.

[26] Seagen's reliance on *GREE* at 5, where prejudice was found where factual information was only disclosed through rebuttal expert reports preventing Plaintiff's experts from opining on the information, is therefore inapplicable here.

[27] *See Mobility Workx*, 2019 WL 5721814, at *6, 8.

[redacted]

information regarding Dr. Bertozzi's mischaracterizations of the emails evaluated by Dr. Lambert. Further, Seagen had the same opportunity to address Dr. Morita's testimony in Dr. Bertozzi's Supplemental Report, eliminating any potential prejudice to Seagen.

Seagen also seeks to strike any reference to Dr. Morita's deposition testimony from Dr. Lambert's report because Seagen asserts that Dr. Morita's testimony allegedly was obtained improperly.[28] Seagen is incorrect. The testimony Dr. Lambert discussed in his report was provided by Dr. Morita in response to issues raised by Seagen during its deposition cross-examination. [redacted].[30] Accordingly, Dr. Morita's testimony was properly responsive, as it was a further explanation, clarification, and correction allegations advanced by Seagen during cross-examination.[31] [redacted]

[28] Dkt. No. 252 at 5-7.

[29] [redacted]

[30] [redacted]

[31] [redacted]

[redacted].[32] As such, Dr. Lambert's reference to Dr. Morita's testimony should not be struck, and the jury should have the opportunity to make its own determination based on a complete record.

III. THE OPINIONS AND EVIDENCE SET FORTH IN DR. LAMBERT'S OPENING REPORT ARE APPROPRIATE FOR THE JURY'S CONSIDERATION IN DECIDING ISSUES OF ENABLEMENT AND WRITTEN DESCRIPTION

A. Dr. Lambert's Opening Report Appropriately Cites Pre-2019 Evidence

In his Opening Report, Dr. Lambert provides his analysis and expert conclusions, *inter alia*, on whether the full scope of each of the Asserted Claims is enabled from the perspective of the POSA.[33] Seagen attempts to limit the evidence and opinions Dr. Lambert would be able to present to the jury on this central issue through several different arguments, none of which support the striking of any portion of Dr. Lambert's report.[34]

Seagen's argument in Section III.A falters on its unstated premise that "post-filing" means "after 2004." The "filing date" of the '039 patent is not 2004—it is July 2019. Seagen has not cross-moved for summary judgment to establish its entitlement to an earlier filing date, and so in the event the Court does not grant summary judgment of invalidity on this basis, the "filing date"

[redacted]

[32] *See* Ex. 2, Lambert Responsive Report ¶¶ 143, 145.
[33] *See* Ex. 1, Lambert Opening Report Section VII.B, ¶ 20; *see also Alcon Research Ltd. v. Barr Labs., Inc.*, 745 F.3d 1180, 1188 (Fed. Cir. 2014) (enablement is viewed from the perspective of the POSA).
[34] *See Pipitone v. Biomatrix, Inc.*, 288 F.3d 239, 249-50 (5th Cir. 2002) (holding the fact-finder entitled to hear expert testimony and decide whether it should accept or reject it after "considering all factors that weigh on credibility," including whether the facts on which the expert relied are accurate).

[redacted]

will be determined at trial. Seagen does not dispute that all the evidence it seeks to strike is admissible if the filing date is July 2019.

Seagen's "Motion to Strike" is thus, at most, a premature request for a limiting instruction. Even so, such an instruction would be inappropriate. Seagen's argument begins with a misstatement of law. Seagen urges the Court to "strike the portions of Dr. Lambert's report where he relies on post-filing evidence."[35] Granting such a sweeping request would be explicitly contrary, however, to the Federal Circuit's *Amgen* decision.[36] As *Amgen* sets forth, post-filing evidence may be relevant to various issues regarding enablement, including whether the patent's examples are "representative" of the claimed scope and whether the patentee could practice its own patent without undue experimentation.[37]

Seagen next identifies swaths of Dr. Lambert's report to strike without substantively discussing what he actually said. As shown below, Seagen's approach is misplaced, and encompasses evidence and analysis that may be relevant and cannot be stricken at this juncture.

Drugs. For example, under the Court's claim construction, the '039 patent claims ADCs containing any drug, "D," and not just the "auristatin" class of drugs exemplified in the patent. Paragraph 194 discusses a class of drugs (duocarmycins) that cannot chemically be attached to the rest of the ADC like the patent's auristatins. Dr. Lambert's discussion of how Seagen subsequently had to invent methods for attaching such drugs, supports that the '039 patent does not teach how to attach such drugs, and that the patentees could not do so at the time, and is thus relevant to enablement of the full scope of the Asserted Claims. Further, Seagen's subsequent patent admits

[35] Dkt. No. 252 at 7.
[36] *Amgen, Inc. v. Sanofi*, 872 F.3d 1367 (Fed. Cir. 2017).
[37] *Id.* at 1374-75; *ALZA Corp. v. Andrx Pharms., LLC*, 603 F.3d 935, 941-43 (Fed. Cir. 2010).

[redacted]

that the spacer taught in the '039 patent is "unlikely to work for all alcohol containing drugs" and that new technologies were needed "to attach drugs heretofore believed to be unsuitable for use as ADCs."[38] These are precisely the types of facts on which the jury can rely to conclude that Seagen did not enable the claims as of its alleged priority date.[39] Paragraphs 264-268 expand on this point, citing additional Seagen publications in this area.

Paragraphs 256-261 make a similar point involving another drug, the original auristatin. The original auristatin had a "tertiary amine," which could not be attached to an ADC by "conventional conjugation technologies."[40] The alleged novelty of the '039 patent family was the addition of a monomethyl group on dolastatin/auristatin compounds (e.g., MMAE) to enable attachment to an ADC. Several years later, Seagen in fact disclosed a new method for attaching auristatins (e.g., Auristatin E) lacking a monomethyl group to an ADC. These facts are relevant to § 112 as explained above, and provide critical context for the jury to understand the '039 patent. Finally, paragraph 217 makes a similar point, discussing another Seagen patent.

Spacers. The '039 patent claims ADCs in which a spacer, "Y_y," connects the tetrapeptide to the drug moiety. Per the Court's construction, there is no limitation on the atoms or structures that comprise the spacer. One issue in this case is whether the patent in fact describes and enables the use of any atoms in that way. In paragraphs 110 and 196, Dr. Lambert discusses non-Seagen ADCs that use "spacers" different from anything disclosed in the '039 patent, to substantiate his

[38] Ex. 1, Lambert Opening Report ¶ 194 (quoting US Pat. No. 11,116,847 at 1:45-49, 1:61-2:3).
[39] Seagen's reliance on *CFMT, Inc. v. Yieldup Int'l Corp.*, 349 F.3d 1333, 1340 (Fed. Cir. 2003) is premised on an incomplete quotation. The Federal Circuit actually wrote: "such developments do not ***alone*** cast doubt on enablement of the original invention." *Id.* at 1340 (emphasis added). The *CMFT* court nowhere suggested such developments were ***irrelevant*** to enablement, instead explaining how they fit into its assessment of the ultimate legal question.
[40] Ex. 1, Lambert Opening Report ¶¶ 256-58.

[redacted]

opinion that the '039 patent's examples do not "permit the POSA to visualize" these other ADCs' spacers. This analysis of structural features of various spacers within the claim scope constitutes precisely the analysis required to assess whether the patent's teachings are sufficient to claim a genus,[41] and this evidence plainly is relevant under *Amgen v. Sanofi*. It cannot be "stricken."

Intracellular Cleavage. Determining whether an ADC is within the '039 patent's scope also requires assessing the functional properties of the ADC, namely, whether it meets the Drug Moiety Intracellular Cleavage Limitation. Dr. Lambert explains in his report how difficult it is to ascertain this property, explaining the patent's lack of guidance and some of his own publications studying this phenomenon. Paragraph 210 analyzes whether some of the '039 patent's ADCs "intracellularly cleave," including discussion of Seagen's scientific publications that show that, in fact, these ADCs do not meet this limitation. These non-functional "examples" are relevant, *inter alia*, to the experimentation required to practice the claim.[42] There is no basis to strike this discussion in the abstract, and certainly no basis to allow Seagen to hide from the jury that its "examples" do not work simply because the proof that they do not work was published after an application was filed. The art cited by Dr. Lambert in paragraphs 305-310 and 314-316 also serves to substantiate his opinions that the patent teaches ***no*** method of determining whether this limitation is met, and that a cancer cell dying is ***not*** proof the ADC intracellularly cleaved.[43]

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[41] *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1350 (Fed. Cir. 2010) (en banc).
[42] *Idenix Pharms. LLC v. Gilead Sci., Inc.*, 941 F.3d 1149, 1160-61 (Fed. Cir. 2019).
[43] Seagen's unexplained citation to *Garlock* appears inapposite. In *Garlock*, the patent taught a method to determine "stretch rate" and the Federal Circuit explained that subsequent developments in polymer technology did not undermine the fact that the patent taught how to determine "stretch rate." *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540 1540, 1551 (Fed. Cir. 1983). Here, the point is that there is no method taught.

[redacted]

B. Dr. Lambert Provides Analysis on the Understanding of the POSA of the Required Structural and Functional Limitations of the Asserted Claims

Seagen's motion also asks the Court to strike myriad paragraphs of Dr. Lambert's analysis, alleging that Dr. Lambert somehow misapprehends the scope of the claims.[44] Seagen's entire argument, however, hinges on a mischaracterization of Dr. Lambert's report that ignores both the statements and context provided in the report itself regarding therapeutic ***viability*** (not ***effectiveness***), and Dr. Lambert's testimony explaining its relevance to the POSA's analysis.[45]

While there is no dispute that the Asserted Claims have structural limitations, and do not contain a limitation requiring that a claimed ADC be therapeutically ***effective***, the Asserted Claims have a functional requirement as well: the Asserted Claims require the ADC's drug moiety to be "intracellularly cleaved in a patient." Section 112(a) requires that a patent's disclosure enable the POSA to make the full scope of the claimed invention without undue experimentation.[46] Enabling the Asserted Claims thus requires that the patent teach both how to make the ADCs ***and*** how to identify the ADCs that possess the required functional characteristic where the drug moiety is capable of being intracellularly cleaved in a patient.[47] Dr. Lambert's report addresses both.

As explained by Dr. Lambert, therapeutic viability is therefore directly tied to evaluating whether the enablement requirement is satisfied as to the full scope of the Asserted Claims, as the POSA must not only be able to make the ADC, but also be able to use the ADC in the way intended

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[44] Seagen's motion to strike attempts to broadly encompass portions of Dr. Lambert's enablement analysis that appropriately address structural and functional limitations, including ones that do not even reference the "therapeutic viability" issue at the core of their argument, for example ¶¶ 128-29. *See, e.g.*, Dkt. No. 252 § III.B; Ex. 1, Lambert Opening Report ¶¶ 128-29.
[45] *See* Ex. 1, Lambert Opening Report ¶¶ 125, 126-29; *see also* Ex. 4, Lambert Tr. at 101:16-23 (discussing therapeutic viability), 102:24-103:2 (same), 103:13-25 (same).
[46] *Idenix*, 941 F.3d at 1154.
[47] *See, e.g.*, *Idenix*, 941 F.3d at 1159.

[redacted]

by the Asserted Claims.[48] In other words, the ADC's drug moiety must intracellularly cleave in a patient to meet the claimed limitations. The '039 patent as a whole also recognizes that the claimed ADC must be administered to patients, meaning evaluating enablement based on structure alone, without consideration of the ADC's use and function would be fruitless.[49]

In view of the limitations of the Asserted Claims, the context of the patent, and the POSA's own knowledge, the POSA would thus need to be able to make a usable ADC—one that could be synthesized, tested, and have sufficient structural integrity to meet the Asserted Claims' functional requirements.[50] As explained by Dr. Lambert during his deposition, [redacted][51] He further stated [redacted][52]

As is evidenced by both Dr. Lambert's report and his testimony, he therefore does not equate "therapeutically viable" with any requirement or level of efficacy, but rather it addresses

[48] *See, e.g.*, Ex. 4, Lambert Tr. at 105:21-106:1; *see also* Ex. 1, Lambert Opening Report Section VII.B, ¶ 20.
[49] *See, e.g.*, '039 patent at Claim 1, 4:25-29 ("Accordingly, there is a clear need in the art for dolastatin/auristatin derivatives having significantly lower toxicity, yet useful therapeutic efficiency."), 10:16-20 ("In yet another aspect, the invention provides methods for preventing cancer including administering to a patient in need thereof an effective amount of a Drug-Ligand Conjugate having a cleavable Drug unit from the Drug-Ligand Conjugate.").
[50] *See, e.g.*, *Idenix*, 941 F.3d at 1159.
[51] Ex. 4, Lambert Tr. at 102:20-103:2.
[52] Ex. 4, Lambert Tr. at 105:21-106:1, 103:19-25 [redacted]

[redacted]

whether the POSA would be enabled to make ADCs meeting the full scope of both the structural and functional limitations of the Asserted Claims without undue experimentation. In fact, Seagen conveniently ignores paragraph 124, which immediately precedes the paragraphs Seagen seeks to strike and refutes its mischaracterization of Dr. Lambert's report: [redacted][53] As such, while the "viability" of an ADC appropriately takes into consideration both the structural and functional limitations of the Asserted Claims, including whether it can be synthesized, placed into a patient, and ultimately be intracellularly cleaved in the patient, therapeutic effectiveness is explicitly excluded from Dr. Lambert's enablement analysis.

C. Dr. Lambert Appropriately Analyzes Written Description

Another central issue in this case is whether the '039 patent adequately describes the claimed genus of ADCs. This can be done in one of two ways: (1) by describing representative examples or (2) by describing "structural features common to the members of the genus so that one of skill in the art can 'visualize or recognize' the members of the genus."[54] The patent discloses zero examples of ADCs beyond those directed to the auristatin/dolastatin class, so Seagen is left to argue that it satisfied this second test, and so moves in Section III.C to strike Dr. Lambert's analysis to prevent the jury from hearing contrary evidence and opinions on this issue.

Paragraphs 92 to 96 of Dr. Lambert's report explain how the auristatins discussed in the patent differ structurally from other drugs, preventing the POSA from using them to "visualize or recognize" the other members of the much broader claimed genus that is unbounded by structure. Paragraphs 108 to 114 make a similar point regarding the patent's discussion of spacers. These

[53] Ex. 1, Lambert Opening Report ¶ 124.
[54] *Ariad*, 598 F.3d at 1350.

[redacted]

analyses inform Dr. Lambert's ultimate opinion (¶¶ 115-120) that the POSA "cannot visualize the claimed genus of ADCs" (¶ 119). Contrary to Seagen's assertion (Mot. at 12), this is the precise question and legal standard set forth in the Federal Circuit's *en banc Ariad* decision. Further, Dr. Lambert's analysis of the patent's disclosure in these paragraphs provide helpful technical background to the jury in applying the Court's jury instruction on this issue.

IV. DR. LAMBERT'S APPROPRIATE ADDITIONAL REFERENCES TO ANALYSIS AND CONCLUSIONS OF OTHERS CONSISTENT WITH HIS OWN

A. Consistency of Opinions Provided in Post-Grant Review Proceedings

Dr. Lambert's citation to the PGR Proceedings does not form the basis for his invalidity opinions, but instead appropriately serves to check the consistency of his analysis with the conclusions reached by others, as envisioned by Rules 702 and 703.[55] In particular, Dr. Lambert previously analyzed and opined upon factual evidence regarding the patentability of the '039 patent, and he incorporates that analysis by reference. Although the PTAB denied institution of that PGR for other reasons unrelated to validity, the PTAB explicitly rejected Seagen's contention that the arguments are "substantively weak."[56] The consistency of the PTAB's analysis with Dr. Lambert's adds credibility to Dr. Lambert's opinions.[57] Questions regarding both Dr. Lambert's substantive opinion and the weight it should be given should be left to the trier of fact.

[55] Ex. 1, Lambert Opening Report ¶ 1 [redacted]

[56] Ex. 5, *Daiichi Sankyo, Inc. v. Seagen Inc.*, PGR2021-00030, Paper 11 (P.T.A.B. June 24, 2021), DSC_ENHERTU_00391577-598 at DSC_ENHERTU_00391595 ("we disagree with Patent Owner that the merits are substantively weak").

[57] None of the cases Seagen cites are dispositive as none of the opinions are regarding motions to strike expert testimony. Regardless, as explained above, Dr. Lambert is not relying on the PGR statements to support his analysis, but to confirm consistency.

[redacted]

B. Consistency with Factual Observations by the European Patent Office

Dr. Lambert's Opening Report also mentions certain statements by the EPO. As contemplated by Rule 703, those statements serve as factual observations regarding Seagen's approach and the state of the art that Dr. Lambert notes are consistent with his own analysis and conclusions regarding validity.[58] This is likewise relevant to the jury's appropriate analysis of the credibility of an expert's opinions and the weight they should be afforded.[59] Seagen again attempts to prevent the jury from receiving a complete record that contradicts its own narrative of the facts.

C. Dr. Lambert Likewise Confirms Consistency with Mr. Manspeizer

Dr. Lambert's citation to Mr. Manspeizer's testimony likewise goes to questions of consistency and reliability. Dr. Lambert and Mr. Manspeizer evaluated many of the same underlying facts in their separate, parallel analyses regarding different issues, and Dr. Lambert notes the consistency of their underlying findings.[60] This issue is thus similarly one of determining the weight of the evidence, rather than the Court determining its admissibility.[61]

V. CONCLUSION

For the reasons explained above, Seagen's motion to strike portions of Dr. Lambert's expert reports should be denied.

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[58] Ex. 1, Lambert Opening Report ¶ 81 [redacted], ¶ 341 [redacted]

[59] *See Mobility Workx*, 2019 WL 5721814, at *6, 8. None of the cases Seagen cites are dispositive as none of the opinions are regarding motions to strike expert testimony, nor do they address a situation where, as here, the expert is merely noting the consistency of certain factual observations with his own analysis.

[60] *See, e.g.*, Ex.1, Lambert Opening Report fn. 114 [redacted]

[61] *Mobility Workx*, 2019 WL 5721814, at *6, 8.

[redacted]

Dated: January 20, 2022

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that all counsel of record who have consented to electronic service are being served with a copy of this document via electronic mail on January 20, 2022.

/s/ Preston K. Ratliff II

[redacted]